Practice Based Audit 2018/19

Valproate medicines safety

Each year pharmacy teams must perform a practice-based audit as part of their contractual requirements for the NHS Pharmacy Contract. Practice-based audits provide an opportunity to review services and procedures within the pharmacy and, having assessed them, decide what can be improved. They can also be used to gather data about pharmacy practice to support closer working with other healthcare professionals as well as service and/or patient experience improvements. Audits must have clear outcomes which will assist in developing patient care.

Background to the 2018/19 audit

Research has shown that there is a significant risk of birth defects and developmental disorders in all children born to women who take valproate-containing medicines during their pregnancy. In April 2018, the Medicines and Healthcare products Regulatory Agency (MHRA) changed the licence for valproate medicines (Epilim, Depakote and generic brands) so these must no longer be prescribed to women or girls of childbearing potential unless they are on a Pregnancy Prevention Programme (PPP).

Previously, efforts to raise awareness of the risks around valproate-containing medicines and pregnancy have not been successful. In 2016, it is suspected that over 400 women taking valproate fell pregnant. The change in licencing is intended to drive behavioural change in healthcare professionals and ensure all patients are fully aware of the risks and the need to avoid becoming pregnant. All girls and women of child bearing potential who are prescribed valproate should have a discussion with their GP, who will arrange for them to have their treatment reviewed by a specialist and for a PPP to be put in place. Each PPP includes the completion of a signed risk acknowledgement form when the patient's treatment is reviewed by a specialist, at least annually. However, no girl or woman of child bearing potential should stop taking valproate without first discussing it with their doctor. Therefore, pharmacists should **always** dispense the prescription (where clinically appropriate, in line with their usual procedures), counselling the patient and advising them to contact their GP if they are not already on a PPP.

In autumn 2018, the regulatory changes will be further supported by smaller pack sizes to encourage monthly prescribing; and a warning image on valproate packaging and blister packs. However, **in the interim**, pharmacists should hand out a patient card and patient booklet when counselling every woman of childbearing potential (age 12-49) who presents in the pharmacy with a prescription for valproate. Pharmacists should also use the boxed warning stickers, especially on split packs, which will be provided by your wholesaler with deliveries. **If you have not received the patient cards, patient booklets and/or warning stickers, please contact Sanofi on 0845 372 7101 or email uk-medicalinformation@sanofi.com.**

This audit will seek to explore community pharmacy's contribution in supporting girls and women of childbearing potential in taking valproate medicines. It will help to inform the monitoring activities of the Valproate Stakeholder Network, convened by the MHRA. The Network will be monitoring the impact of the new risk minimisation measures, by looking at knowledge/behavioural changes, prescribing rates, use of PPPs, GP referrals to specialists, incidences of pregnancy, and any unintended impacts.

The audit is split into four sections.

- **Section 1** will gather information on your understanding/awareness of the risks associated with valproate and pregnancy
- **Section 2** will support you in proactively identifying patients who may be at risk, using your PMR system
- **Section 3** will gather information on the patients you encounter who are at risk, and what actions you take to support them
- **Section 4** will record your learnings and reflections from carrying out the audit, and what further actions you will take

Valproate safety practice-based audit

Instructions for completing the audit

You will need to complete the audit twice: once in **July 2018 (Phase 1)** and then again in **November 2018 (Phase 2)**.

The audit should be **completed in stages,** as certain sections of the audit should be **completed by specific dates**, as outlined below. If you have a patient safety champion in your pharmacy team, they may wish to take the lead on this audit. **Remember, a copy of all completed audit paperwork must be kept in the pharmacy as these may be required during contract monitoring visits.**

When to complete each section

	Phase 1	Phase 2
Audit section	**Deadlines (starting 1 July 2018)**	**Deadlines (starting 1 November 2018)**
Section 1 (Pre-audit survey)	8 July 2018	11 November 2018
Section 2 (PMR analysis)	8 July 2018	11 November 2018
Section 3 (Patient data collection)	31 July 2018	30 November 2018
Section 4 (Post-audit reflections)	31 July 2018 – ongoing	30 November 2018 – ongoing
DATA SUBMISSION	31 August 2018	31 January 2019

How to complete each section

- **Section 1 (Pre-audit survey)** should be completed by the pharmacy professional leading this audit, before you begin the other sections. It is important to answer all questions honestly. This will help us understand how well messages about the risks involving valproate medicines have been communicated.
- **Section 2 (PMR analysis)** should be completed once you have completed Section 1, in the first week of the audit month, by the deadline specified above.
- **Section 3 (Quantitative patient data collection)** includes Table 1 and Table 2. These two tables should be completed **throughout the whole audit month**. The tables should be filled out **every time a prescription for valproate is presented for a female patient, aged 12-49**. Where clinically appropriate and in line with usual checking procedures, the prescription should still be dispensed to the patient, even if they are not on a PPP.
- **Section 4 (Post-audit reflections)** should be used to document reflections on the audit as well as changes that you intend to make to the ways in which you support patients on valproate medicines.

Data submission

Once you have completed all four sections of the audit, collate and submit your data to inform a national analysis report via
Phase 1 – https://www.surveymonkey.co.uk/r/valproateP1 (live from 31 July 2018 until 31 August 2018)
Phase 2 – https://www.surveymonkey.co.uk/r/valproateP2 (live from 30 November 2018 until 31 January 2019)

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Section 1 – Pre-audit survey

To be completed in the **first week of the audit month**

Were you aware of the risks of abnormal pregnancy outcomes associated with the use of valproate medicines during pregnancy **before** reading the background information to this audit?	☐ Yes ☐ No
Are/were the other members of your pharmacy dispensing team aware of the risks of abnormal pregnancy outcomes associated with the use of valproate medicines during pregnancy?	☐ Yes ☐ Some ☐ No
If you answered yes to either of the questions above, what actions have you and the pharmacy team taken **to date** to support the safety of girls and women being treated with valproate? (select all that apply)	☐ Discussed risks with team ☐ Discussed risks with relevant patients ☐ Added notes to PMR ☐ Handed out patient alert cards ☐ Handed out patient booklets ☐ Used 'no pregnancy' stickers ☐ Used dispensing label warnings ☐ Conducted a full medication review (e.g. MUR) ☐ Other (please specify) _____
Were you aware of the strengthened regulatory position (as of April 2018) regarding valproate medicines? i.e. that valproate is now **contraindicated** in girls and women of child-bearing potential (age 12-49) unless a **Pregnancy Prevention Programme** is in place?	☐ Yes ☐ No
How were you made aware of this? (select all that apply)	☐ Superintendent / MSO communication ☐ Regulator communication (GPhC/PSNI) ☐ Professional body communication (RPS/PFNI) ☐ MHRA Drug Safety Update ☐ Letter from GP ☐ LPC communication ☐ Other (please specify) _____

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Section 2 – PMR analysis

To be completed in the **first week of the audit month**

Task:

Using your PMR system, proactively identify all patients who meet the eligibility criteria for this audit i.e. patients who:

- Are **female** AND;
- Are **aged 12-49** AND;
- Are taking a **valproate-containing medicine** (valproic acid, sodium valproate).

What is the total number of patients on your PMR who meet all three of these criteria? *

Actions:

- Check whether an automatic electronic warning/alert appears on your PMR system for each patient.
- **Make a record on the PMR** for each eligible patient, so that you and other members of your team are notified that, when a prescription comes in for this patient, a *sensitive conversation* (ideally in the consultation room) should be had with them to ensure they are made aware of the risks around valproate medicines and pregnancy.
- Where clinically appropriate, and in line with usual checking procedures, the prescription should still be dispensed to the patient, even if they advise that they are not on a PPP yet and even if they advise they are already pregnant (in these instances, you should also notify their GP). A record of the conversation and any notifications sent to their GP should also be recorded on their PMR.

* *If the total number of patients on your PMR system is **zero**, continue to be alert to any prescriptions for valproate which come in for a female patient aged 12-49 throughout the audit period, ensuring you have a sensitive conversation with the patient and complete Section 3 for those prescriptions which do come in. If no prescriptions come in, still ensure you complete Section 1 and Section 4 of the audit and retain these within the pharmacy.*

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Section 3 – Quantitative patient data collection

Make records in **Table 1** and **Table 2** for every valproate prescription you dispense during the audit period for a female patient aged between 12 and 49 (inclusive). If you encounter more than five patients during the one-month audit period, please use further copies of this page, updating the individual patient numbers accordingly.

Table 1 – Tick the relevant boxes, using one row per patient

Individual patient number	**Patient age**	**Details of valproate medicine prescribed**				Is there an **indication on the prescription** (e.g. in endorsements or notes for dispenser) that a **PPP** is in place for this patient?
		Name	Modified release?	Duration of treatment	Total **daily dose**	
1	☐ 12-18 ☐ 19-29 ☐ 30-39 ☐ 40-49	☐ Epilim ☐ Epival ☐ Depakote ☐ Orlept ☐ Convulex ☐ Generic ☐ Episenta ☐ Other	☐ Yes ☐ No	☐ < 28 days ☐ 28 days ☐ 56 days ☐ > 56 days	☐ < 400mg ☐ 400-800mg ☐ 801-1000mg ☐ >1000mg	☐ Yes ☐ No Record this on the patient's PMR
2	☐ 12-18 ☐ 19-29 ☐ 30-39 ☐ 40-49	☐ Epilim ☐ Epival ☐ Depakote ☐ Orlept ☐ Convulex ☐ Generic ☐ Episenta ☐ Other	☐ Yes ☐ No	☐ < 28 days ☐ 28 days ☐ 56 days ☐ > 56 days	☐ < 400mg ☐ 400-800mg ☐ 801-1000mg ☐ >1000mg	☐ Yes ☐ No Record this on the patient's PMR
3	☐ 12-18 ☐ 19-29 ☐ 30-39 ☐ 40-49	☐ Epilim ☐ Epival ☐ Depakote ☐ Orlept ☐ Convulex ☐ Generic ☐ Episenta ☐ Other	☐ Yes ☐ No	☐ < 28 days ☐ 28 days ☐ 56 days ☐ > 56 days	☐ < 400mg ☐ 400-800mg ☐ 801-1000mg ☐ >1000mg	☐ Yes ☐ No Record this on the patient's PMR
4	☐ 12-18 ☐ 19-29 ☐ 30-39 ☐ 40-49	☐ Epilim ☐ Epival ☐ Depakote ☐ Orlept ☐ Convulex ☐ Generic ☐ Episenta ☐ Other	☐ Yes ☐ No	☐ < 28 days ☐ 28 days ☐ 56 days ☐ > 56 days	☐ < 400mg ☐ 400-800mg ☐ 801-1000mg ☐ >1000mg	☐ Yes ☐ No Record this on the patient's PMR
5	☐ 12-18 ☐ 19-29 ☐ 30-39 ☐ 40-49	☐ Epilim ☐ Epival ☐ Depakote ☐ Orlept ☐ Convulex ☐ Generic ☐ Episenta ☐ Other	☐ Yes ☐ No	☐ < 28 days ☐ 28 days ☐ 56 days ☐ > 56 days	☐ < 400mg ☐ 400-800mg ☐ 801-1000mg ☐ >1000mg	☐ Yes ☐ No Record this on the patient's PMR

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Section 3 – Quantitative patient data collection (continued)

Table 2 – Tick the relevant boxes, using <u>one column per patient</u>

Individual patient number	1	2	3	4	5	6	7	8	9	10	Total
Is the patient physically present in the pharmacy?											
Yes											
No – patient representative present											
No – delivery patient											
What actions have you taken to raise awareness of the risks around valproate and pregnancy to this patient? (tick all that apply)											
Supplied patient alert card											
Supplied patient booklet											
Used electronic dispensing label warning											
Used 'no pregnancy' sticker											
For patients present in pharmacy:											
Counselled to reinforce risks											
Conducted review of all medication (e.g. MUR)											
For patients not present in pharmacy:											
Counselled patient representative (if appropriate)											
Made request for patient to contact pharmacist											
Did you refer the patient to their GP?											
Yes – signposted patient to speak to GP											
Yes – contacted GP directly											
No											
Did the patient proactively volunteer any information to indicate that they are already pregnant?											
Yes											
No											
Not applicable (patient not present)											
Have you recorded the actions taken for this patient on their PMR?											
Yes											
Some											
No											

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Section 4 – Post-audit reflections

Use this section to record what you have learned, what changes you are going to make to your practice and how you will share this learning with others. This part of the audit is to be **kept in the pharmacy** and may be inspected during any contract-monitoring visit that is undertaken. If you are in England, you may also wish to use some of the information from this section to form part of your **patient safety report** element of the Quality Payment Scheme.

What are the key learning points you made whilst conducting this audit?

What actions have you taken and/or how have you changed your practice because of these learning points?

How have the key learning points been shared? (select all that apply)

☐ Discussed with pharmacy team
☐ Shared with LPC colleagues
☐ Shared with locum pharmacists
☐ Discussed with local GP surgeries
☐ Other (please specify) _____

What else do you plan to do? (select all that apply)

☐ Discuss learning with pharmacy team
☐ Share with LPC colleagues
☐ Share with locum pharmacists
☐ Discuss with local GP surgeries
☐ Create revalidation (CPD) entry
☐ Appoint a 'valproate champion' in your pharmacy
☐ Other (please specify) _____

Now you have completed all four sections of the audit, collate and submit your data to inform the national analysis report via:
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Further information about valproate use and safety can also be found online at www.medicines.org.uk. Enter 'valproate' in the search box and then click on 'Risk Materials'.